

Application No. (if known): 10/725,246

Attorney Docket No.: 03269/100M292-US3

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Information Disclosure Statement (2 pages)
Form PTO/SB-08 (2 pages) and 16 References
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Docket No.: 03269/100M292-US3
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kenneth NEWMAN et al.

Serial No.: 10/725,246

Art Unit: 1614

Confirmation No.: 1944

Filed: December 1, 2003

Examiner: Not Yet Assigned

Title: METHOD OF TREATING ACUTE PAIN WITH A UNITARY DOSAGE
FORM COMPRISING IBUPROFEN AND OXYCODONE

July 15, 2004

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement (IDS) is submitted in accordance with 37 C.F.R. §§1.97 and 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed before the mailing date of a first office action on the merits

In accordance with 37 C.F.R. 1.98, this IDS includes a list (form PTO/SB/08) of all patents, publications, or other information submitted for consideration by the office. A copy of each document listed is attached, except for the U.S. patents and published U.S. patent

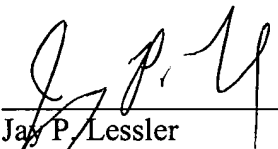
applications. In a Notice published on August 5, 2003 (1276 Official Gazette 55), the USPTO waived the requirement for submitting copies of each cited U.S. patent and U.S. patent application publication in an Information Disclosure Statement for all U.S. patent applications filed after June 30, 2003. The present application was filed after June 30, 2003. Pursuant to this Notice, copies of the U.S. patents and U.S. patent application publications cited in the accompanying PTO/SB/O8 are not submitted herewith.

In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56(b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and applicants reserve the right to prove that the date of publication is in fact different.

No fee is believed to be due with this submission. If, however, any fee is due with this submission, the Commissioner is authorized to charge the fee up to \$2,000.00 to Deposit Account No. 04-0100.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,



Jay P. Lessler
Registration No. 41,151
Attorney for Applicant(s)

DARBY & DARBY P.C.
805 Third Avenue
New York, N.Y. 10022
(212) 527-7700



PTO/SB/08a/b (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/725,246-Conf. #1944
				Filing Date	December 1, 2003
				First Named Inventor	Kenneth Newman
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	2	Attorney Docket Number	03269/100M292-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	US-4,569,937	02-11-1986	Baker et al	
	AB	US-6,103,219	08-15-2000	Sherwood et al	
	AC	US-6,242,004-B1	06-05-2001	Rault	
	AD	US-6,294,195-B1	09-25-2001	Oshlack et al	
	AE	US-6,399,101-B1	06-04-2002	Frontanes et al	
	AF	US-6,471,994-B1	10-29-2002	Staniforth et al	
	AG	US-2002/00068084-A1	06-06-2002	Staniforth	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		
	CA	Cooper, S.A., et al. (1993) "Analgesic efficacy of an ibuprofen-oxycodone combination" Clin. Pharmacol. Ther. February, 1993; Abstract PII-9.		
	CB	Dionne, R. (1999) "Additive analgesic effects of oxycodone and ibuprofen in the oral surgery model" J. Oral Maxillofac Surg. 57:673-678.		
	CC	Drugs R&D (2002) "Oxycodone/ibuprofen" 3:56-57		
	CD	Merck Manual of Diagnosis and Therapy (1999) 17th Ed., pp. 1363-1374.		
	CE	Palangio, M. et al (2000) "Dose-response effect of combination hydrocodone with ibuprofen in patients with moderate to severe postoperative pain" Clin Ther 22(8):990-1002.		
	CF	Palangio, M. et al (2000) "Combination hydrocodone and ibuprofen versus combination oxycodone and acetaminophen in the treatment of postoperative obstetric or gynecologic pain" Clin Ther 22(5):600-612.		
	CG	Raffa, R.B. (2001) "Pharmacology of oral combination analgesics: rational therapy for pain" J. Clin. Pharmacy and Therap. 26:257-264.		
	CH	Staimbaugh, J. (1988) "The combination of ibuprofen and oxycodone/acetaminophen in the management of chronic cancer pain" Clin. Pharmacol. Ther. 44(6):665-669.		
	CI	Sunshine, A., et al (1993) "Analgesic efficacy of ibuprofen hydrocodone vs. ibuprofen alone for the treatment of acute postoperative pain" Pharmacol. Ther. February, 1993; Abstract PII-8.		

Examiner Signature		Date Considered	
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Substitute for form 1449A/B/PTO <h1>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h1> <i>(Use as many sheets as necessary)</i>				Complete if Known	
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				Art Unit	1614
				Examiner Name	Not Yet Assigned
				Attorney Docket Number	03269/100M292-US3
Sheet	2	of	2		

CJ	VanDyke, T.E., et al (2003) "Oxycodone + ibuprofen combination significantly improves analgesia compared with oxycodone or ibuprofen alone" Poster No. 1384 Presented at 32nd Annual Meeting and Exhibition of the AADR (March 12-15, 2003).
CK	Singla, N. et al (2004) "The combination of oxycodone HC1 and ibuprofen compared with either component alone is statistically and clinically superior in alleviating post gynecological surgery pain". Poster No. 882 Presented at APS/CPS 2nd Joint Scientific Meeting (May 6-9, 2004).
CL	Kapil, R. et al (2003) "The effect of food on the absorption of an oxycodone/ibuprofen combination tablet following a single dose administration." Poster No. 82 Presented at 104th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (April 2-5, 2003).
CM	Kapil, R. et al (2003) "Comparison of bioequivalency of single-dose oxycodone/ibuprofen combination with oxycodone or ibuprofen alone." Poster No. 46 Presented at 104th Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics (April 2-5, 2003).
CN	Newman, K. et al (2003) "Combination of oxycodone HC1 and ibuprofen compared to ibuprofen or oxycodone HC1 alone is more rapid and effective in alleviating postoperative pain". Poster No. 907 Presented at the 22nd Annual Scientific Meeting of the American Pain Society (March 20-23, 2003).
CO	Christensen, S. et al (2003) "Oxycodone + ibuprofen combination significantly improves analgesia compared with oxycodone or ibuprofen alone". Poster Presented at 19th Annual Meeting of the American Academy of Pain Medicine (February 18-23, 2003).
CP	Heydorn, W. and Zheng, H. (2003) "Oxycodone/Ibuprofen Combination Therapy Is Safe and Well Tolerated By Patients With Postoperative Pain" Poster No. 922 Presented at the 22nd Annual Scientific Meeting of the American Pain Society (March 20-23, 2003).

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature		Date Considered	
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